Attorney Docket No. 7593 CO1
Customer No. 49459

REMARKS

Rejection based upon 35 U.S.C. §103

A. Chattoraj et al. in view of Ridgway and McNeel

Claims 1-17 have been rejected under 35 U.S.C. §103(a) as being obvious over Chattoraj et al. in view of Ridgway et al. and McNeel et al.

Applicants respectfully traverse the Examiner's rejection.

1. Description of Cited Art

Chatteroraj et al. discloses a method of monitoring both the planktonic and sessile microbial populations in an industrial water system, including boilers and cooling towers, comprising the steps of: a) adding a fluorogenic dye directly into said industrial water system and allowing said fluorogenic dye to react with any planktonic or sessile microbiological organisms present; b) providing means for measurement of the fluorescent signals of said fluorogenic dye in said industrial water system, with the first fluorescent signal measurement being that of the fluorogenic dye and the second fluorescent signal measurement being that of the reacted fluorogenic dye; c) using said means for measurement of said fluorescent signals of said fluorogenic dye to measure the fluorescent signal of the fluorogenic dye and the fluorescent signal of the reacted fluorogenic dye, while discarding any measured fluorescent signal values below a predetermined noise level; d) calculating the Ratio of the measured fluorescent signal of the reacted fluorogenic dye to the fluorescent signal of the fluorogenic dye; and e) monitoring the change in calculated Ratio from step d) to determine the status of the planktonic and sessile microbiological populations in the industrial water system. This reference also discloses the additional steps of: 1) determining the optimal amount of biocide to be delivered to the industrial water system wherein said optimal amount is based upon the magnitude of said Ratio or the rate of change of said Ratio; and 2) delivering said optimal amount of biocide to the industrial water system. Moreover, the fluorogenic agent can be fed either by itself or in combination with water treatment agents that are typically fed into a cooling water system such as, but not limited to, scale

and corrosion inhibitors. Chattoraj does not specifically discuss the application of its monitoring technique to a membrane separation system.

Ridgway teaches how biofouling is a widespread problem limiting the performance and application of reverse osmosis and other membrane separation processes. The primary source of microbial contamination is typically the system feedwater; surface waters in particular contain high numbers of microorganisms which lead to microbial problems. With respect to monitoring and detecting membrane foulants, Ridgeway teaches the use of optical microscopy, scanning and transmission microscopy, atomic force microscopy, x-ray fluorescence emission microscopy, attenuated total reflection Fourier transform infrared spectrometry (ATR-FTIR), energy-dispersive x-ray microanalysis, and Auger spectroscopy. The reference also teaches that the information obtained from optical microscopy can be extended and quantified by the use of organic dyes which preferentially react with fluorescent probes such as 2,4-diamidino-2-phenylindole, 5-cyano-2,3-ditoyl tetrazolium chloride, and rhodamine. All these techniques directly measure membrane fouling with the detriment that the membrane has to be destroyed and extracted from the membrane system. Nowhere is there any mention of monitoring biofouling in a membrane separation system by fluorescence.

McNeel teaches a composition and method of controlling fouling in an aqueous system that contains a membrane separation system, e.g. a reverse osmosis membrane. More specifically, the composition contains an anionic antiscalant and a cationically charged biocide. Testing included the measurement of biocide in a permeate stream, a concentrate stream, and a feed stream by a Total Organic Carbon (TOC) test.

2. Analysis

One of ordinary skill in the art would not have been lead to make the claimed invention because one of ordinary skill in the art would be lead to combine the teachings of the prior art, unless they have the benefit of hindsight, which is not allowed.

An obviousness analysis is an objective analysis and the following factors play a role in this analysis: (1) the scope and content of the prior art is determined; (2) the differences between the prior art and the claims at issue are to be ascertained; and (3) the

level of ordinary skill in the pertinent art resolved. *KSR International Co. v. Teleflex Inc.* 127 S.Ct. 1727 at 1734 (2007). After these facts are collected, the ultimate question is whether there is an apparent reason to combine the known elements in the fashion claimed by the patent at issue. *Id.* at 1734.

In the case where a patent application is directed to a combination of elements, "it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine elements in the way the claimed invention does." *Id.* at 1741. This inquiry is especially difficult in a case where the differences in the prior art are more than a mere substitution of one element for another. (*See Id.* at 1740, stating the following: "these principles may be difficult in other cases than it is here because the claimed subject matter may involve more than a simple substitution of one known element for another....) A non-rigid application of the teaching-suggestion motivation tests is relevant to an inquiry of obviousness because it protects against hindsight reconstruction. *Id.* at 1742-1743. Moreover, a non-obviousness analysis requires a look into the predictability of the art that claimed invention falls in. *Id.* at 1739.

The disclosures, which form the basis of the Examiner's rejection, convey the following understanding in the art: fluorescence can be used as a tool for monitoring biofouling in an industrial water system and not specifically a membrane separation system and that the level of microorganisms in a system can be determined by adding a fluorogenic agent that reacts with the microorganisms in the system; and the presence of foulants in a reverse osmosis membrane system can be monitored when the membrane separation system is shut down, the membrane is extracted, and the membrane is subsequently analyzed out of the system, e.g. by reacting a portion of the membrane with a fluorescent dye for the presence of foulants (staining). The disclosures also teach that the total organic content (TOC) in a permeate stream, concentrate stream, and a feed stream have been measured to see whether a biocide is effective in reducing membrane fouling.

The claimed invention pertains to a method of monitoring biofouling in a membrane separation process by reacting a fluorogenic agent with at least one microorganism in the concentrate stream and the feed stream.

Applicants rebut the Examiner's argument because Applicants contend that one of ordinary skill in the art would not be motivated to combine the three references because they all involve completely different techniques for monitoring a biological species/system: measuring of a fluorogenic agent added to an industrial water system and not specifically a membrane separation system (Chattoraj); measuring the fluorescence of a membrane separation by dismantling a membrane (Ridgeway); and measuring microbiological activity via a total organic carbon test (McNeel). It would be unlikely to that one of ordinary skill in the art would combine select teachings of knowledge/pick or choose parts of disclosures in formulating the claimed invention when all three disclosures involve completely different techniques for monitoring biological species. Without some explicit motivation in the references it would be unlikely that one would be motivated to combine the teachings of the prior art to formulate the invention. The *KSR* opinion does not foreclose the application of the teaching, suggestion and motivation test and in fact supports this test to protect against hindsight reconstruction, when said test is not applied rigidly. *Id.* at 1742-1743. Therefore, the lack of motivation in the art to combine the references is relevant to an inquiry of obviousness and based upon the facts of the present case, Applicants contend that the facts way in favor of a non-obviousness finding.

Applicants further contend that the fact that the claimed invention configuration is not a simple case of substituting one element for another lends itself to a determination of non-obviousness. When dealing with claimed subject matter that involves more than a simple substitution of one known element for another, the inquiry is more difficult, and "it is often necessary for a court to look to the interrelated teachings of multiple patents...all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue." *Id.* at 1740-1741. In the present case, there would be no apparent reason to combine a fluorescence-based destructive membrane protocol (Chatorraj) with a fluorescence-based nondestructive protocol and non-fluorescence based protocol (McNeel). Moreover, Applicants contend that there really are no interrelated teachings among the art because they are so different from one another. Therefore, based upon the fact that the claimed invention would require a complete reconfiguration and alignment of the elements found in the prior art

and the fact there is no apparent reason found in the prior art to combine the teachings, the claimed invention is non-obvious.

Applicants further contend that predictability of the art lends itself to a finding that the claims are non-obvious. This case is not akin to switching or combining two known mechanical parts. Membrane separations systems are dynamic environments subject to a lot of factors, especially considering the addition of a chemistry to the system may cause fouling of the membrane separation system and reduced system performance; in other words membrane separation systems do not lend themselves to being manipulated or reconfigured that easily. Therefore, the fact that membrane separation systems are dynamic in nature supports a finding that the claims are nonobvious.

Therefore based upon the totality of circumstances and not applying the teaching suggestion and motivation test rigidly, Applicants contend that claim 1 is nonobvious.

Considering that claims 2-17 depend upon an allowable base claim, claim 1, Applicants request that the Examiner allow claims 2-17.

Rejection based upon Double Patenting

a. Chattoraj in view of Ridgeway and McNeel

Claims 1-5 and 9-17 have been rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15 of U.S. Patent No. 6,329,165 B1 in view of Ridgway et al and McNeel.

Applicants respectfully traverse the Examiner's rejection.

1. Description of Cited Art

Chatteroraj et al. discloses a method of monitoring both the planktonic and sessile microbial populations in an industrial water system, including boilers and cooling towers, comprising the steps of: a) adding a fluorogenic dye directly into said industrial water system and allowing said fluorogenic dye to react with any planktonic or sessile microbiological organisms present; b) providing means for measurement of the fluorescent signals of said fluorogenic dye in said industrial water system, with the first fluorescent signal measurement being that of the fluorogenic dye and the second

fluorescent signal measurement being that of the reacted fluorogenic dye; c) using said means for measurement of said fluorescent signals of said fluorogenic dye to measure the fluorescent signal of the fluorogenic dye and the fluorescent signal of the reacted fluorogenic dye, while discarding any measured fluorescent signal values below a predetermined noise level; d) calculating the Ratio of the measured fluorescent signal of the reacted fluorogenic dye to the fluorescent signal of the fluorogenic dye; and e) monitoring the change in calculated Ratio from step d) to determine the status of the planktonic and sessile microbiological populations in the industrial water system. This reference also discloses the additional steps of: 1) determining the optimal amount of biocide to be delivered to the industrial water system wherein said optimal amount is based upon the magnitude of said Ratio or the rate of change of said Ratio; and 2) delivering said optimal amount of biocide to the industrial water system. Moreover, the fluorogenic agent can be fed either by itself or in combination with water treatment agents that are typically fed into a cooling water system such as, but not limited to, scale and corrosion inhibitors. Chattoraj does not specifically discuss the application of its monitoring technique to a membrane separation system.

Ridgway teaches how biofouling is a widespread problem limiting the performance and application of reverse osmosis and other membrane separation processes. The primary source of microbial contamination is typically the system feedwater; surface waters in particular contain high numbers of microorganisms which lead to microbial problems. With respect to monitoring and detecting membrane foulants, Ridgeway teaches the use of optical microscopy, scanning and transmission microscopy, atomic force microscopy, x-ray fluorescence emission microscopy, attenuated total reflection Fourier transform infrared spectrometry (ATR-FTIR), energy-dispersive x-ray microanalysis, and Auger spectroscopy. The reference also teaches that the information obtained from optical microscopy can be extended and quantified by the use of organic dyes which preferentially react with fluorescent probes such as 2,4-diamidino-2-phenylindole, 5-cyano-2,3-ditoyl tetrazolium chloride, and rhodamine. All these techniques directly measure membrane fouling with the detriment that the membrane has to be destroyed and extracted from the membrane system. Nowhere is

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2. Analysis

One of ordinary skill in the art would not have been lead to make the claimed invention because one of ordinary skill in the art would be lead to combine the teachings of the prior art, unless they have the benefit of hindsight, which is not allowed.

An obviousness analysis is an objective analysis and the following factors play a role in this analysis: (1) the scope and content of the prior art is determined; (2) the differences between the prior art and the claims at issue are to be ascertained; and (3) the level of ordinary skill in the pertinent art resolved. *KSR International Co. v. Teleflex Inc.* 127 S.Ct. 1727 at 1734 (2007). After these facts are collected, the ultimate question is whether there is an apparent reason to combine the known elements in the fashion claimed by the patent at issue. *Id.* at 1734.

In the case where a patent application is directed to a combination of elements, "it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine elements in the way the claimed invention does." *Id.* at 1741. This inquiry is especially difficult in a case where the differences in the prior art are more than a mere substitution of one element for another. (*See Id.* at 1740, stating the following: "these principles may be difficult in other cases than it is here because the claimed subject matter may involve more than a simple substitution of one known element for another....) A non-rigid application of the teaching-suggestion motivation tests is relevant to an inquiry of obviousness because it protects against hindsight reconstruction. *Id.* at 1742-1743. Moreover, a non-obviousness analysis requires a look into the predictability of the art that claimed invention falls in. *Id.* at 1739.

The disclosures, which form the basis of the Examiner's rejection, convey the following understanding in the art: fluorescence can be used as a tool for monitoring biofouling in an industrial water system and not specifically a membrane separation system and that the level of microorganisms in a system can be determined by adding a fluorogenic agent that reacts with the microorganisms in the system; and the presence of foulants in a reverse osmosis membrane system can be monitored when the membrane separation system is shut down, the membrane is extracted, and the membrane is subsequently analyzed out of the system, e.g. by reacting a portion of the membrane with a fluorescent dye for the presence of foulants (staining). The disclosures also teach that the total organic content (TOC) in a permeate stream, concentrate stream, and a feed stream have been measured to see whether a biocide is effective in reducing membrane fouling.

The claimed invention pertains to a method of monitoring biofouling in a membrane separation process by reacting a fluorogenic agent with at least one microorganism in the concentrate stream and the feed stream.

Applicants rebut the Examiner's argument because Applicants contend that one of ordinary skill in the art would not be motivated to combine the three references because they all involve completely different techniques for monitoring a biological species/system: measuring of a fluorogenic agent added to an industrial water system and not specifically a membrane separation system (Chattoraj); measuring the fluorescence of a membrane separation by dismantling a membrane (Ridgeway); and measuring microbiological activity via a total organic carbon test (McNeel). It would be unlikely to that one of ordinary skill in the art would combine select teachings of knowledge/pick or choose parts of disclosures in formulating the claimed invention when all three disclosures involve completely different techniques for monitoring biological species. Without some explicit motivation in the references it would be unlikely that one would be motivated to combine the teachings of the prior art to formulate the invention. The *KSR* opinion does not foreclose the application of the teaching, suggestion and motivation test and in fact supports this test to protect against hindsight reconstruction, when said test is not applied rigidly. *Id.* at 1742-1743. Therefore, the lack of motivation in the art to combine the references is relevant to an inquiry of obviousness and based upon the facts

of the present case, Applicants contend that the facts way in favor of a non-obviousness finding.

Applicants further contend that the fact that the claimed invention configuration is not a simple case of substituting one element for another lends itself to a determination of non-obviousness. When dealing with claimed subject matter that involves more than a simple substitution of one known element for another, the inquiry is more difficult, and "it is often necessary for a court to look to the interrelated teachings of multiple patents...all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue." *Id.* at 1740-1741. In the present case, there would be no apparent reason to combine a fluorescence-based destructive membrane protocol (Chatorraj) with a fluorescence-based nondestructive protocol and non-fluorescence based protocol (McNeel). Moreover, Applicants contend that there really are no interrelated teachings among the art because they are so different from one another. Therefore, based upon the fact that the claimed invention would require a complete reconfiguration and alignment of the elements found in the prior art and the fact there is no apparent reason found in the prior art to combine the teachings, the claimed invention is non-obvious.

Applicants further contend that predictability of the art lends itself to a finding that the claims are non-obvious. This case is not akin to switching or combining two known mechanical parts. Membrane separations systems are dynamic environments subject to a lot of factors, especially considering the addition of a chemistry to the system may cause fouling of the membrane separation system and reduced system performance; in other words membrane separation systems do not lend themselves to being manipulated or reconfigured that easily. Therefore, the fact that membrane separation systems are dynamic in nature supports a finding that the claims are nonobvious.

Therefore based upon the totality of circumstances and not applying the teaching suggestion and motivation test rigidly, Applicants contend that claim 1 is nonobvious.

Considering that claims 2-5 and 9-17 depend upon an allowable base claim, claim 1, Applicants request that the Examiner allow claims 2-5 and 9-17.

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CONCLUSION

Applicants respectfully request that a Notice of Allowance be sent for all pending claims.

Respectfully Submitted,

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